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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,155	07/14/2003	Douglas T. Gjerde	P002.210	9520

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PHYNEXUS, INC.
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EXAMINER

RAMILLANO, LORE JANET

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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12/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/620,155

Applicant(s)

GJERDE ET AL.

Examiner

Lore Ramillano

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 25-34 is/are pending in the application.
- 4a) Of the above claim(s) 25-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/4/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. In applicant's reply filed on 10/4/07, applicant amended claims 1, 5, 8, 13, 18, and 21. Claims 1-22 and 25-34 are pending. Claims 1-22 are under examination.

Response to Amendment

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-22, under 35 U.S.C. 112, second paragraph, is withdrawn.

Prior art rejections

3. The rejections over the prior art are maintained.
4. With regard to the Hunt reference (PG Pub. No. 2002/0110495), while examiner indicated in paragraph 14 in the last Office action (filed on 8/30/07) that this cited reference may be referenced as Smith, it appears that examiner has provided sufficient information for applicant to recognize and locate the cited reference. Examiner indicated that the reference was called Hunt and provided the correct citation in the last Office action. Furthermore, because Hunt was cited by applicant in their IDS filed on 12/7/05, it is not necessary to cite the reference again in the PTO-892 form.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-3, 9, 10, 14, 15, and 19-22** are rejected under 35 U.S.C. 102(b) as being anticipated by Colpan (US 5652141).

Colpan discloses an extraction column comprising: a column body (40) having an open end, an open lower end, and an open channel between the upper and lower end of the column body; a bottom frit (23) bonded to and extending across the open channel, the bottom frit having a low pore volume; a top frit (23) bonded to and extending across the open channel between the bottom frit and the open upper end of the column body, and top frit having a low pore volume; the top frit and bottom frit are less than 350 microns thick (i.e. column 3, line 65 to column 4, line 11); the top frit, bottom frit, and channel surface define an extraction media chamber (between 23 and 23); and a bed of extraction (20) media positioned inside the extraction media chamber (i.e. column 3, lines 14-44).

Colpan further discloses that the bottom frit is located at the open lower end of the column body; the bottom frit is a membrane screen and the top frit is a membrane screen, which comprises a polymeric material; the column body comprises polypropylene; membrane screen made of nylon or polyester; a column body attached to a peristaltic pump; and a lower tubular member comprising the lower end of the column body, a first engaging end, and a lower open channel between the lower end of the column body and the first engaging end; and an upper tubular member comprising the upper end of the column body, a second engaging end, and an upper open channel between the upper end of the column body and the second engaging end, the top membrane screen of the extraction column bonded to and extending across the upper open channel at the second engaging end, wherein the first engaging end engages the second engaging end to form a sealing engagement (i.e. column 3, line 14 to column 4, line 33).

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. **Claim 1** is rejected under 35 U.S.C. 103(a) as being unpatentable over Brewer (US 6566145) in view of Colpan.

In figure 2, Brewer discloses an extraction column comprising: a column body (10) having an open end, an open lower end, and an open channel between the upper and lower end of the column body; a bottom frit (24) bonded to and extending across the open channel, the bottom frit having a low pore volume; a top frit (22) bonded to and extending across the open channel between the bottom frit and the open upper end of the column body, and top frit having a low pore volume; the top frit, bottom frit, and channel surface define an extraction media chamber (between 22 and 24); and a bed of extraction (18) media positioned inside the extraction media chamber (i.e. column 3, lines 3-36).

Brewer does not specifically disclose a frit less than 350 microns thick.

Colpan discloses a device comprising two filter layers made of nylon with equal pore sizes, and a cylindrical hollow body. The particle size of the filter layer is in the range of from 5 microns to 500 microns at a total thickness of the filter layer of from 0.1 to 200 mm. (i.e. column 3, line 14 to column 4, line 11). It would have been obvious to a person of ordinary skill in the art to modify Brewer's frits to have the specific filter dimensions as disclosed by Colpan because it would be desirable to have frits especially customized for microscale-sized chromatography columns.

9. **Claims 1-6, 9-12, 14-15, and 18-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hargro ("Hargro," US 6139733) in view of Colpan.

In figure 2, Hargro discloses an extraction column comprising: a column body (22) having an open end, an open lower end, and an open channel between the upper and lower end of the column body; a bottom frit (26) bonded to and extending across the open channel, the bottom frit having a low pore volume; a top frit (22) bonded to and extending across the open channel between the bottom frit and the open upper end of the column body, and top frit having a low pore volume; the top frit, bottom frit, and channel surface define an extraction media chamber (between 22 and 26); and a bed of extraction (28) media positioned inside the extraction media chamber (i.e. column 2, lines 30-42).

Hargro further discloses that the bottom frit is located at the open lower end of the column body (Fig. 2); the extraction media comprises a packed bed of gel-type packing material (i.e. column 2, lines 37-42); the extraction media comprises an affinity binding group (i.e. column 2, lines 37-42); the column body comprises polyethylene (i.e. column 4, lines 15-20); a syringe (fig. 6); an upper end of the column body is attached to a pump (14, fig. 1); and a lower tubular member comprising the lower end of the column body, a first engaging end, and a lower open channel between the lower end of the column body and the first engaging end; and an upper tubular member comprising the upper end of the column body, a second engaging end, and an upper open channel between the upper end of the column body and the second engaging end, the top membrane screen of the extraction column bonded to and extending across the upper open channel at the second engaging end, wherein the first engaging end engages the second engaging end to form a sealing engagement (i.e. Fig. 1, 2, 5, and 6; column 2, lines 30-41).

Hargro does not specifically disclose a frit less than 350 or 200 microns thick; a frit having a pore volume equal to 10% or less; a frit having a pore volume of 1 microliter or less; and a membrane screen made of nylon.

Colpan discloses a device comprising two filter layers made of nylon with equal pore sizes, and a cylindrical hollow body. The particle size of the filter layer is in the range of from 5 microns to 500 microns at a total thickness of the filter layer of from 0.1 to 200 mm. (i.e. column 3, line 14 to column 4, line 11). It would have been obvious to a person of ordinary skill in the art to modify Hargro's frits to have the specific filter dimensions and filter material as disclosed by Colpan because it would be desirable to have frits especially customized for microscale-sized chromatography columns.

10. **Claims 7 and 13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hargro in view of Colpan, as applied to claims 1-6, 9-12, 14-15, and 18-22 above, and further in view of Smith et al. ("Smith," US Pub. No. 2004/0253687).

The disclosure of Hargro is discussed above. Modified Hargro does not specifically disclose utilizing agarose and sepharose and an affinity binding group, such as Protein A.

Smith discloses an apparatus for extracting proteins of interest comprising an "affinity tag," which is a molecule, ligand or polypeptide attached to a protein (polypeptide) of interest. Examples of affinity tags include, but are not limited to, hexa-histidine, other metal tags, Protein A, and other protein or small molecule tags which may assist in the isolation and purification of expressed proteins. Furthermore, Smith discloses an "affinity matrix," which include chromatography medium, such as agarose, cellulose, Sepharose, Sephadex and other chromatography medium, polystyrene beads, magnetic beads, filters, membranes and other solid-state materials bound to

ligands or substrates which bind to the affinity tag of choice. (i.e. [0052]-[0053], [0084]). It would have been obvious to a person of ordinary skill in the art to modify the modified Hargro by specifically utilizing sepharose or agarose since the modified Hargro discloses utilizing chromatography medium, which is a term commonly known in the art that pertains to gel-based chromatography media, such as agarose and cellulose. In addition, it would have been obvious to a person of ordinary skill in the art to modify the modified Hargro by specifically utilizing Protein A as the affinity tag because the modified Hargro discloses utilizing a media which is known in the art to contain materials that bind to an affinity tag of choice. Thus, it would be desirable to have Protein A as the affinity tag of choice to isolate particular protein complexes bound to the tagged protein of interest.

11. **Claims 8 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hargro in view of Colpan, as applied to claims 1-6, 9-12, 14-15, and 18-22 above, and further in view of Hunt et al. ("Hunt," US Pub. No. 2002/0110495).

The disclosure of Hargro is discussed above. Modified Hargro does not specifically disclose having a bed volume of less than 20 microliters and an extraction media chamber at most 1000 microliters.

Hunt discloses a device for the purification and separation of substances. The purification device comprises a sample holder comprising a sample chamber and a column module. The column module is securable to the sample holder and is packed with chromatography medium having a special affinity for attracting a given substance. (abstract). Hunt further discloses a microcolumn with a single bed volume, 0.02 to 0.1 ml, in paragraph [0020]. It would have been obvious to a person of ordinary skill in the art to modify the modified Hargro by specifically having a bed

volume of less than 20 microliters and an extraction media chamber at most 1000 microliters because it would be advantageous to utilize microscale-sized components for a microscale chromatography column.

12. **Claim 17** is rejected under 35 U.S.C. 103(a) as being unpatentable over Hargro in view of Colpan, as applied to claims 1-6, 9-12, 14-15, and 18-22 above, and further in view of Halmann et al. ("Halmann," US 4302534).

The disclosure of Hargro is discussed above. Modified Hargro does not specifically disclose having a bed of extraction media having a dry weight of less than 10 mg.

Halmann discloses a heterogenous enzymatic immunoassay, in which chemiluminescence is employed as a detection means. Halmann discloses in example 2, a standard assay procedure comprising about 1mg dry weight of anti-SEB-Sepharose, solution to be tested, and saline solution (i.e. column 7, lines 1-40). It would have been obvious to a person of ordinary skill in the art to modify the modified Hargro by specifically utilizing less than 10mg dry weight of Sepharose because it would be beneficial to utilize a limited amount of chromatography media for microscale sized chromatography columns to insure a reasonable amount of chromatography media is packed inside the column.

Response to Arguments

13. Applicant's arguments filed 10/4/07 have been fully considered but they are not persuasive.

In response to arguments in sections IV (A) to V (E):

In response to applicant's argument that Colpan's layer (23) is not the same as applicant's frit because applicant's extraction columns do not have a filtering function, examiner does not find this argument convincing. First, the specification in the published application recites in paragraph

[0064] that "[t]he term "frit" as used herein are defined as porous material for holding the extraction media in place in a column. An extraction media chamber is typically defined by a top and bottom frit positioned in an extraction column. In preferred embodiments of the invention the frit is a thin, low pore volume filter, e.g, a membrane screen." Furthermore, the specification in paragraph [0134] recites that "[t]he frits of the invention, e.g., a membrane screen, can be made from any material that has the required physical properties as described herein. Examples of suitable materials include nylon, polyester, polyamide, polycarbonate, cellulose, polyethylene, . . ." Based on these cited paragraphs, it appears that Colpan's layer (23) reads on applicant's frit because Colpan discloses in EXAMPLE 2, for instance, that his layer (23) is a 50 μ m PE (an abbreviation known in the art for polyethylene) frit or a nylon net and is capable of holding diol-diatomaceous earth (i.e. extraction media). Thus, because Colpan discloses a frit made of either PE (polyethylene) or nylon, which is the same material applicant uses to make his frit, Colpan's layer (23) inherently comprises the same properties recited by applicant.

In response to applicant's argument that Colpan does not disclose a frit that is less than 350 microns thick, examiner disagrees. Colpan discloses, which applicant also recognizes, in column 3, line 65 to column 4, line 11, a frit that is 50 μ m.

Election/Restrictions

14. This application contains claim 25-34 drawn to an invention nonelected with traverse in the reply filed on 6/5/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

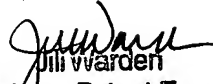
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Lore Ramillano
Examiner
Art Unit 1797


Jill Warden
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